REMARKS

The amendments above and the remarks below are in response to an Office Action mailed on October 20, 2008. To reduce confusion, previously non-existent Claim 128 has been listed as canceled. Previously withdrawn Claims 1-28, 37-38, 84-98 and 109-115 have been canceled but applicant reserves the right to pursue these claims in future continuation or divisional applications. New Claims 151-152 have been added and thus only Claims 79-83, 107, 108 and 121-152 are pending. Of those, Claims 79-83, 107, 108 and 121-150 were rejected under 35 U.S.C. 102(e) over U.S. Pat. No. 5,876,367 to Kaganov et al. ("Kaganov").

To allow consideration of this response and amendment, a request for continued examination (RCE) has been submitted. A request for **One-Month** extension of time in which to respond to the aforementioned Office Action is also filed concurrently herewith.

Kaganov

Kaganov discloses methods and devices for protecting a patient from embolization during arteriotomy procedures. In particular, Kaganov provides a bypass tubing or indwelling shunt, having a main lumen for blood bypass and a second, branching lumen adapted to receive an elongated blood filtration instrument and to allow passage of the instrument into an artery distal to an endarterectomy region.

Applicants further note the record indicates that at the time the inventions of the present application were made, the present application and the Kaganov reference were owned by, or subject to an obligation of assignment to, the same entity. In particular, the Kaganov reference was assigned to Embol-X, Inc., by an assignment executed on February 4, 1997. Likewise, the priority application of the present application, U.S. Application No. 08/852,867, filed on May 8, 1997, and ultimately issued as U.S. Patent No. 5,911,734, was assigned to Embol-X, Inc., by an assignment executed on October 21, 1997. Under 35 U.S.C. § 103(c), Kaganov is, therefore, precluded from subsequently being combined with other references in support of a § 103(a) obviousness rejection.

Independent Claim 79

Applicants respectfully submit that amended Claim 79 is not anticipated by Kaganov because the reference does not teach all of the recitations of amended Claim 79. For example, Claim 79 has been amended to recite a stent supported by an outside surface of a guide member. This same guide member also defines a lumen in which is disposed a means for filtering material from a blood stream and a means for deploying the means for filtering. For example, Figure 2 discloses a filter device that would be read upon by Claim 79.

Applicants respectfully submit that Kaganov does not disclose the filter device recited by Claim 79. Kaganov mentions a stent only twice. In the first instance, Kaganov describes a stent as being deployed on its own catheter through a branching lumen of bypass tubing. No mention is made of the stent catheter also deploying a filtering device.

In one embodiment, the invention provides a bypass tubing or indwelling shunt, having a main lumen for blood bypass and a second, branching lumen adapted to receive an elongated blood filtration instrument, or other surgical device (e.g., an angioplasty catheter, stent catheter, atherectomy catheter) and to allow passage of same into an artery distal to the endarterectomy region. The branching secondary lumen can either merge and communicate with the main lumen of the shunt, or may extend to a distal opening separate from the blood bypass lumen of the device.

Col. 2; Il. 5-15 of Kaganov. In the second instance, Kaganov references a stent only to describe timing of its deployment. No reference is made to the physical relationship between the filter and stent

Insertion of the filter device may occur distal to the arteriotomy site, the shunt, and the occlusion clamp through an introducer, either intraoperatively or percutaneously. Where insertion of the filter device occurs percutaneously, distal to the region, the filter device may be inserted and deployed prior to interventional therapy such as arteriotomy, angioplasty, or stent deployment.

Col. 10; Il. 32-35 of Kaganov. Accordingly, Applicants respectfully submit that Kaganov does not teach all the limitations now recited in Claim 79 and that the § 102(e) rejection of Claim 79 based on Kaganov should, therefore, be withdrawn.

Independent Claim 107

Independent Claim 107 now recites a stent mounted around the sleeve that applies a restraining force to the struts of the filter device. As described above, Kaganov only discloses a stent separately deployed with its own catheter. Accordingly, Applicants respectfully submit that Kaganov does not teach all the limitations now recited in Claim 107 and that the § 102(e) rejection of Claim 107 based on Kaganov should, therefore, be withdrawn.

Independent Claim 129

Claim 129 now recites a stent supported by an introducer sheath with a lumen that contains an expansion frame and filter mesh. For similar reasons to those found above, Applicants respectfully submit that Kaganov does not teach all the limitations now recited in Claim 129 and that the § 102(e) rejection of Claim 129 based on Kaganov should, therefore, be withdrawn.

Independent Claim 145

Claim 145 now recites a stent coupled to and extending around a guidewire that supports a filter membrane. As described above, Kaganov's disclosure of a stent appears to be limited to use on its own dedicated catheter without a filter. Accordingly, Applicants respectfully submit that Kaganov does not teach all the limitations now recited in Claim 145 and that the § 102(e) rejection of Claim 145 based on Kaganov should, therefore, be withdrawn.

Dependent Claims 80-83, 107-108, 121-125, 127-144, and 146-150

Claims 80-83, 107-108, 121-125, 127-144, and new Claims 146-150 depend from independent claims 79, 107, 129, and 145. Applicants respectfully submit that these dependent claims are patentable over the cited reference for at least the same reasons set forth above with respect to amended Claims 79, 107, 129, and 145, in addition to the patentable subject matter recited in each dependent claim. Accordingly, Applicants respectfully request that the § 102(e) rejection be withdrawn and that these dependent claims, as well as the newly added dependent claims, be allowed.

New Claims 151 and 152

The new claims recite a filter assembly mounted in a catheter lumen and a balloon and stent mounted on the catheter. These claims should also be allowable over Kaganov.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance and have made a good faith effort to respond to the outstanding Office Action. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is cordially invited to contact Applicants' attorney, at the telephone number below, to resolve any such issues promptly.

Any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on solely that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the cited reference shows or teaches, even if not expressly discussed herein. For purposes of this response, we have treated the cited reference as prior art, but Applicants respectfully reserve the right to challenge later whether the cited reference is prior art. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; amendments, such as the inclusion of a stent in each of the independent claims, are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter.

The Commissioner is hereby authorized to charge the required fees for the filing of this paper, including the Request for RCE and One-Month extension of time, to Deposit Account No. 50-1225. No additional fees are believed to be due. However, if an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge said fees, such as under 37 C.F.R. §§ 1.16 or 1.17, or to credit any overpayment, to Deposit Account No. 50-1225 referencing Attorney Docket No. RMI-5730CON6.

Respectfully submitted,

Date: February 20, 2009

/Gregory J. Carlin#45607/

Carlin, Gregory J. Registration Number 45607 Edwards Lifesciences LLC

Law Department One Edwards Way Irvine, California 92614

Telephone: (949) 250-6893 Facsimile: (949) 250-6850 Customer No. 30452